

# EXHIBIT A

## Case Summary

**Case Number:** BER L-002257-22

**Case Caption:** Gutierrez Maria Vs Medtronic Plc

**Court:** Civil Part

**Venue:** Bergen

**Case Initiation Date:** 04/21/2022

**Case Type:** Product Liability

**Case Status:** Active

**Jury Demand:** 6 Jurors

**Case Track:** 3

**Judge:** Peter G Geiger

**Team:** 2

**Original Discovery End Date:**

**Current Discovery End Date:**

**# of DED Extensions:** 0

**Original Arbitration Date:**

**Current Arbitration Date:**

**# of Arb Adjournments:** 0

**Original Trial Date:**

**Current Trial Date:**

**# of Trial Date Adjournments:** 0

**Disposition Date:**

**Case Disposition:** Open

**Statewide Lien:**

### Plaintiffs

**Maria Gutierrez**

**Party Description:** Adm Ad Prsqndum

**Attorney Name:** Edmund V Mc Cann

**Address Line 1:** 152 Philips Avenue

**Address Line 2:**

**Attorney Bar ID:** 270321971

**City:** South Hackensack      **State:** NJ

**Zip:** 07606

**Phone:**

**Attorney Email:** EMCCANN@MCCANN-MCCANN.COM

### Defendants

**Medtronic Plc**

**Party Description:** Corp

**Attorney Name:**

**Address Line 1:** 480 Washington Blvd.

**Address Line 2:**

**Attorney Bar ID:**

**City:** Jersey City      **State:** NJ

**Zip:** 07310

**Phone:**

**Attorney Email:**

**Covidien Lp**

**Party Description:** Prtnrship

**Attorney Name:**

**Address Line 1:** 480 Washington Blvd.

**Address Line 2:**

**Attorney Bar ID:**

**City:** Jersey City      **State:** NJ

**Zip:** 07310

**Phone:**

**Attorney Email:**

### Case Actions

Filed Date	Docket Text	Transaction ID	Entry Date
04/21/2022	Complaint with Jury Demand for BER-L-002257-22 submitted by MC CANN, EDMUND V, MC CANN & MC CANN on behalf of MARIA GUTIERREZ against MEDTRONIC PLC, COVIDIEN LP	LCV20221624656	04/21/2022
04/22/2022	TRACK ASSIGNMENT Notice submitted by Case Management	LCV20221628155	04/22/2022
04/22/2022	CLERK NOTICE: re: Complaint [LCV20221624656] -The data entered in eCourts (data) does not match the information contained in the document(s). In order to correct data, a motion must be made pursuant to R. 1:5-6.	LCV20221635258	04/22/2022
04/22/2022	CLERK NOTICE: re: Complaint [LCV20221624656] -Please be advised that ACMS has been updated to reflect DTC as indicated on the complaint.	LCV20221635261	04/22/2022
08/22/2022	AFFIDAVIT OF SERVICE submitted by MC CANN, EDMUND, V of MC CANN & MC CANN on behalf of MARIA GUTIERREZ against MEDTRONIC PLC, COVIDIEN LP	LCV20223038254	08/22/2022
09/03/2022	LACK OF PROSECUTION DISMISSAL WARNING Notice submitted by Case Management	LCV20223171097	09/03/2022

McCann & McCann, Esqs.  
Edmund V. McCann, Esq.  
Attorney ID # 270321971  
238 Main Street  
Post Office Box 399  
Ridgefield Park, NJ 07660  
(201) 440-4880  
(201) 440-6392 (fax)  
Attorney(s) for Plaintiff(s)  
emccann@mccann-mccann.com

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Maria Gutierrez ) SUPERIOR COURT OF NEW JERSEY  
                  ) LAW DIVISION- BERGEN COUNTY  
                  Plaintiff(s), )  
                  vs.                 ) Docket No.  
                  )  
Medtronic's plc and Covidien LP ) Civil Action  
John Doe (A through L)         ) COMPLAINT AND JURY DEMAND  
Company (M through Z) these names  
Being fictitious                 )  

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Defendants )

Plaintiff, Maria Gutierrez, residing at 152 Phillips Avenue, S. Hackensack, NJ 07606, by and through their attorneys, McCann & McCann, Esqs. (Edmund V. McCann, Esq., appearing), by way of Complaint, says:

Device Use

Ventilators, often referred to as life support machines, are used in intensive care units to aid and assist patients who cannot breathe on their own. Throughout the course of the recent COVID-19

pandemic, and with consideration to the lung damage caused by the subject virus, many of the patients were placed on a ventilator in order to allow the machine to take over this vital body function and allow the patient to rest and to heal.

The Puritan Bennett™ 980, a ventilator which had been in service for many years, reputedly enabled patients to breathe more naturally through an innovative breath delivery technology system. However, according to an FDA database, a manufacturing assembly error was discovered in which a capacitor, placed within the machine incorrectly, could cause the device to become inoperable during use. In response to the device defect, Medtronic's North Haven, Connecticut-based Covidien unit initiated the recall for the Puritan Bennett 980 Series Ventilator on Nov. 4, 2021. Medtronic warned users to remove the affected ventilators from clinical service and to quarantine the affected ventilators until a Medtronic technical service engineer had inspected and replaced the affected printed circuit board assemblies.

There have been previous recalls and updates related to the Puritan Bennett 980 Series system, including a 2018 software update to the external USB drive performance and its impact on graphical user interface (GUI) functionality. The update also covered the labeling displayed on the GUI during ventilator use and included product enhancements. In 2015, the system had a Class I recall as a result of an error that can cause air delivery volume to be lower than necessary.

#### PARTIES

Plaintiff, Maria Gutierrez, is a citizen of the State of New Jersey residing at 152 Phillips Avenue, S. Hackensack, NJ 07606.

At all times referenced hereto, Maria Gutierrez and Hector Garcia-Nunez were husband and wife.

Defendants, Medtronic's plc and Covidien LP ("Manufacturing Defendants") with offices located at 480 Washington Blvd., Jersey City, NJ 07310 design and manufacture products called ventilators, devices intended to mechanically control or assist patient breathing by delivering a predetermined percentage of oxygen in the breathing gas. These Defendants held themselves out to the medical and lay communities generally, and to Plaintiff Hector Garcia-Nunez, in particular, as manufacturers, providers and sellers of medical devices, including ventilators.

The Fictitiously named Defendants A through L are believed to have been involved in placing the device in the stream of commerce or the physicians and medical staff who may have failed to monitor the device or ignore the indications of the defective equipment.

#### FACTUAL BACKGROUND

Hector Garcia-Nunez was employed by a printing company who became afflicted with Covid-19. on April 3, 2020, Mr. Garcia-Nunez was hospitalized in Hackensack Meridian Hospital as a result of an affliction with what has been described as covid-19. Immediately following admission, the treating doctors place Mr. Garcia-Nunez on a Puritan Bennett 980 Series Ventilator.

The ventilator used at the time was designed, manufactured, marketed, distributed and sold to Hackensack Meridian Hospital by Defendant Medtronic's plc and Covidien LP, and as a result of the aforementioned defect in the Puritan Bennett 980 Series Ventilator, Mr. Garcia-Nunez suffered a loss of ventilation which resulted serious adverse events such as hypercarbia (an increase of carbon dioxide in the blood), hypoxemia (an abnormally low amount of oxygen in the bloodstream), neurological injury and death.

#### COUNT I NEGLIGENCE

1. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.
2. At all times relevant to this action, Defendants had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research, development, manufacture, inspection, labeling, marketing, promotion and sale of the ventilation equipment, which Defendants Medtronic's plc and Covidien LP and those Defendants identified as M through Z introduced into the stream of commerce, including a duty to ensure that users would not suffer from unreasonable, dangerous or untoward adverse side effects.
3. At all times relevant to this action, Defendants had a duty to warn all health care providers and consumers of the risks, dangers, and adverse side effects of ventilators and the Defendants named as A through L were the physicians and medical staff who failed to monitor the device or ignored the indications that the device was not functioning properly.
4. At all times relevant to this action, Defendants knew or reasonably should have known that the ventilators were unreasonably dangerous and defective when used as directed and as designed, including but not limited to the following particulars;

Based on what they knew or reasonably should have known as described above, the Defendants deviated from principles of due care, deviated from the standard of care, and were otherwise negligent in one or more of the following particulars:

- a. In failing to conduct those tests and studies necessary to determine that the use of the Puritan Bennett 980 Series Ventilator could be dangerous and contraindicated for use;

- b. In failing to provide to the medical community adequate instructions for the safe use of the devices;
  - c. In failing to disclose to the medical community that the effectiveness of the Puritan Bennett 980 Series Ventilator was uncertain;
  - d. Manufacturing a product designed to deliver, over time, dangerously high doses of medication directly into shoulder tissue; and
  - e. Promoting the Puritan Bennett 980 Series Ventilator for use despite the fact that the device was not on the authorized list of ventilators approved by the Federal Drug Administration during the COVID-19 pandemic.
5. At all relevant times, Defendants knew or reasonably should have known that the capacitor manufacturing assembly error may cause the ventilator to become inoperable or stop working as intended when used as directed and designed, including but not limited to the following particulars:

Failure of Ventilation which could result in serious adverse events such as hypercarbia (an increase of carbon dioxide in the blood), hypoxemia (an abnormally low amount of oxygen in the bloodstream), neurological injury and death;

6. The product defects alleged above were a substantial contributing cause of the injuries and damages suffered by Plaintiffs.
7. The injuries and damages suffered by Plaintiffs were the reasonably foreseeable results of Defendants' negligence.
8. As a direct and proximate cause of the Defendants' negligence, Plaintiff suffered the loss of her husband in addition, substantial monetary losses and other damages.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, for compensatory damages, plus interest, costs and attorneys' fees.

COUNT II  
STRICT LIABILITY

9. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.
10. Plaintiff is in the class of persons that the Defendants should reasonably foresee as being subject to the harm caused by defectively designed ventilators insofar as Plaintiff Hector Garcia-Nunez was the type of person for whom the ventilators were intended to be used.
11. Defendants, and those named as M through Z which are engaged in the business of selling the products, manufactured and supplied ventilators and placed them into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.
12. The ventilators supplied to Plaintiff were defective in design and formulation and unreasonably dangerous when they left the hands of Defendants, the manufacturers and suppliers, and they reached the user and consumer of the products, Plaintiff, without substantial alteration in the condition in which they were sold.
13. The ventilator devices manufactured by Defendants were unreasonable and dangerously defective beyond the extent contemplated by ordinary patients with ordinary knowledge regarding these products.
14. Defendants' ventilators were defective due to inadequate warning and/or inadequate clinical trials, in vivo and in vitro testing and study, and inadequate reporting regarding the results of such studies.

15. Defendants' ventilators were defective due to inadequate testing, post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury from their ventilators, they failed to provide adequate warnings to the medical community and patients and continued to promote the products as safe and effective.
16. The product defects alleged above were a substantial contributing cause of the injuries suffered by Plaintiff. Specifically, the ventilators caused Plaintiff to suffer the loss of her husband in addition, substantial monetary losses and other damages

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, for compensatory damages, plus interest, costs and attorneys' fees.

### COUNT III

#### STRICT PRODUCTS LIABILITY: FAILURE TO WARN

17. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.
- 19 Defendants manufactured ventilators and placed them into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the products.
20. Defendants' ventilators were defective due to inadequate warning and/or inadequate clinical trials, in vivo and in vitro testing and study, and inadequate reporting regarding the results.
21. Defendants' ventilators were defective due to inadequate post-marketing warning or instruction because, after Defendants knew or should have known of the risk of injury from

their ventilators, they failed to provide adequate warnings to the medical community and patients and continued to promote the ventilators and anesthetics used in the pumps as safe and effective.

22. The defective warnings and labeling on the ventilators and anesthetics used in the pumps were substantial factors in bringing about the injuries to the Plaintiff.

23. As the direct and proximate cause of the defective condition of ventilators as manufactured and/or supplied by Defendants, and specifically their failure to warn, and their negligence, carelessness, other wrongdoing and actions described herein, Plaintiff suffered those injuries and damages as described with particularity, above.

24. As a direct and proximate cause of the Defendants' negligence, Plaintiff suffered the loss of her husband in addition, substantial monetary losses and other damages

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, for compensatory damages, plus interest, costs and attorneys' fees.

#### COUNT IV

#### LOSS OF CONSORTIUM

25. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein.

26. Plaintiff, Maria Gutierrez, was at all times relevant hereto the spouse of Plaintiff Hector Garcia-Nunez and lived and cohabited with him.

27. Maria Gutierrez has been caused, presently and in the future, to suffer the loss of her spouse's companionship, services, society, support and the marital association between husband and wife has been altered and impaired.

WHEREFORE, Plaintiffs pray for judgment against Defendants, jointly and severally, for compensatory damages, plus interest, costs and attorneys' fees.

McCANN & McCANN, ESQS.  
  
Edmund V. McCann  
Attorneys for Plaintiff

Dated:

DESIGNATION OF TRIAL COUNSEL

Pursuant to R.4:25-4, EDMUND V. McCANN, ESQ., is designated as trial counsel herein.

CERTIFICATION PURSUANT TO RULE 1:38-7(b)

I certify that confidential personal identifiers have been redacted from documents now submitted to the court and will be redacted from all documents submitted in the future in accordance with Rule 1:38-7(b).

CERTIFICATION

I hereby certify, pursuant to Rule 4:5-1, that:

1. The within matter is not the subject of any action pending in any other court or arbitration;
2. No other action or arbitration proceeding is contemplated; and
3. No other necessary party to be joined to the subject litigation is presently known.

I hereby certify that the foregoing pleading has been served within the time provided

by the Court Rules.

McCANN & McCANN, ESQS.  
  
EDMUND V. McCANN  
Attorneys for Plaintiff

Dated:

# Civil Case Information Statement

## Case Details: BERGEN | Civil Part Docket# L-002257-22

**Case Caption:** GUTIERREZ MARIA VS MEDTRONIC PLC

**Case Initiation Date:** 04/21/2022

**Attorney Name:** EDMUND V MC CANN

**Firm Name:** MC CANN & MC CANN

**Address:** 238 MAIN ST PO BOX 399

RIDGEFIELD PARK NJ 07660

**Phone:** 2014404880

**Name of Party:** PLAINTIFF : Gutierrez, Maria

**Name of Defendant's Primary Insurance Company**

(if known): None

**Case Type:** PRODUCT LIABILITY

**Document Type:** Complaint with Jury Demand

**Jury Demand:** YES - 6 JURORS

**Is this a professional malpractice case?** NO

**Related cases pending:** NO

**If yes, list docket numbers:**  
**Do you anticipate adding any parties (arising out of same transaction or occurrence)?** NO

**Are sexual abuse claims alleged by:** Maria Gutierrez? NO

## THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

**Do parties have a current, past, or recurrent relationship?** NO

**If yes, is that relationship:**

**Does the statute governing this case provide for payment of fees by the losing party?** NO

**Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:**

**Do you or your client need any disability accommodations?** NO

**If yes, please identify the requested accommodation:**

**Will an interpreter be needed?** NO

**If yes, for what language:**

**Please check off each applicable category:** Putative Class Action? NO Title 59? NO Consumer Fraud? NO

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with Rule 1:38-7(b)

04/21/2022

Dated

/s/ EDMUND V MC CANN

Signed

BERGEN COUNTY COURTHOUSE  
SUPERIOR COURT LAW DIV  
BERGEN COUNTY JUSTICE CTR RM 415  
HACKENSACK NJ 07601-7680

TRACK ASSIGNMENT NOTICE

COURT TELEPHONE NO. (201) 221-0700  
COURT HOURS 8:30 AM - 4:30 PM

DATE: APRIL 21, 2022  
RE: GUTIERREZ MARIA VS MEDTRONIC PLC  
DOCKET: BER L -002257 22

THE ABOVE CASE HAS BEEN ASSIGNED TO: TRACK 3.

DISCOVERY IS 450 DAYS AND RUNS FROM THE FIRST ANSWER OR 90 DAYS  
FROM SERVICE ON THE FIRST DEFENDANT, WHICHEVER COMES FIRST.

THE PRETRIAL JUDGE ASSIGNED IS: HON ESTELA M. DE LA CRUZ

IF YOU HAVE ANY QUESTIONS, CONTACT TEAM 003  
AT: (201) 527-2600.

IF YOU BELIEVE THAT THE TRACK IS INAPPROPRIATE YOU MUST FILE A  
CERTIFICATION OF GOOD CAUSE WITHIN 30 DAYS OF THE FILING OF YOUR PLEADING.  
PLAINTIFF MUST SERVE COPIES OF THIS FORM ON ALL OTHER PARTIES IN ACCORDANCE  
WITH R.4:5A-2.

ATTENTION:

ATT: EDMUND V. MC CANN  
MC CANN & MC CANN  
238 MAIN ST  
PO BOX 399  
RIDGEFIELD PARK NJ 07660

ECOURTS

Maria Gutierrez

Plaintiff

SUPERIOR COURT OF NEW JERSEY  
LAW DIVISION: BERGEN COUNTY

vs

Medtronic's plc and Covidien LP, et al

Defendant

Docket Number  
BER-L-002257-22

**Person/Entity to be served (Name & Address):**

Medtronic's plc a/k/a Meditron Devices Inc. | 51 James Way, Eatontown, NJ 07724

**AFFIDAVIT OF SERVICE**

(For Use by Private Service)

**Attorney:**

McCann & McCann, Esqs.  
238 Main Street Ridgefield Park, NJ 07660

Cost of Service pursuant to R. 4:4-3 (c)

\$ \_\_\_\_\_

**Papers Served:** Summons, Complaint and Jury Demand, Track Assignment Notice and Civil Case Information Statement

**Service Data:**

Served Successfully x Not Served \_\_\_\_\_

Date: 8/17/2022 Time: 4:44 PM

Attempts: \_\_\_\_\_

Name of Person Served and relationship / title:

**Dorothy Cocozziello / Authorized Agent**

**Actual Place of Service:**

**51 James Way, Eatontown, NJ 07724**

**Description of Person Accepting Service:**

Sex: Female Age: 40 - 49 Yrs Height: 5ft8in - 5ft11in Weight: 125 -149 Lbs.

Skin Color: White Hair Color: Black



223117

**Unserved:**

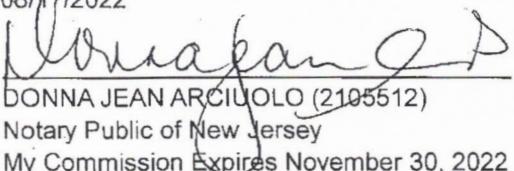
- ( ) Defendant is unknown at the address furnished by the attorney  
( ) All reasonable inquiries suggest defendant moved to an undetermined address  
{ ) No such address in municipality  
{ ) No response on: \_\_\_\_\_ Date \_\_\_\_\_ Time \_\_\_\_\_  
                        Date \_\_\_\_\_ Time \_\_\_\_\_

( ) Not served see comment below

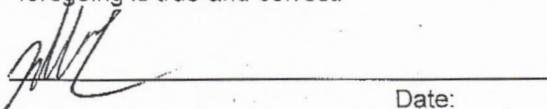
Comments or Remarks:

**Server Data:**

Subscribed and Sworn to before me on  
08/17/2022

  
DONNA JEAN ARCIUOLO (2105512)  
Notary Public of New Jersey  
My Commission Expires November 30, 2022

I, Jake Callahan, was at the time of service a competent adult not having a direct interest in the litigation. I declare under penalty of perjury that the foregoing is true and correct.

  
Date: \_\_\_\_\_

BERGEN COUNTY COURTHOUSE  
SUPERIOR COURT LAW DIV  
BERGEN COUNTY JUSTICE CTR RM 415  
HACKENSACK NJ 07601-7680

DISMISAL NOTICE

TELEPHONE - (201) 527-2600, NICOLE MANALIO TEAM 002  
COURT HOURS: 8:30 AM - 4:30 PM

DATE: SEPTEMBER 02, 2022  
RE: GUTIERREZ MARIA VS MEDTRONIC PLC  
DOCKET: BER L -002257 22  
PARTY: COVIDIEN LP

PLEASE TAKE NOTICE THAT ON NOVEMBER 01, 2022 (60 DAYS FROM DATE OF THIS NOTICE), THE COURT WILL DISMISS THE ABOVE PARTY OR PARTIES FOR LACK OF PROSECUTION WITHOUT PREJUDICE, PURSUANT TO RULE 1:13-7 OR RULE 4:43-2 UNLESS ACTION REQUIRED UNDER THE ABOVE RULES IS TAKEN.

HON PETER G. GEIGER

---

JUDGE

ATT: EDMUND V. MC CANN  
MC CANN & MC CANN  
238 MAIN ST  
PO BOX 399  
RIDGEFIELD PARK NJ 07660